

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

SOUTHEASTERN PENNSYLVANIA
TRANSPORTATION AUTHORITY, JANE
DOE, and JOHN DOE, individually and on
behalf of all others similarly situated,

Plaintiffs,

v.

GILEAD SCIENCES, INC.,

Defendant.

Case No. 2:14-cv-06978-SD

CLASS ACTION

JURY TRIAL DEMANDED

**PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANT'S
MOTION TO DISMISS THE FIRST AMENDED CLASS ACTION COMPLAINT**

Nicholas E. Chimicles
Benjamin F. Johns
Joseph B. Kenney
CHIMICLES & TIKELLIS LLP
One Haverford Centre
361 West Lancaster Avenue
Haverford, PA 19041
Telephone: (610) 642-8500
Facsimile: (610) 649-3633
Nick@chimicles.com
BFJ@chimicles.com
JBK@chimicles.com

Attorneys for Plaintiffs

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I. INTRODUCTION

This litigation presents the federal judiciary with a pointed challenge: to determine whether the law has any role in the heated public debate over a significant public policy issue involving the affordability of and patient access to Gilead Sciences, Inc.'s Hepatitis C ("HCV" or "Hep C") drugs, given the unique and extraordinary circumstances presented here.

Gilead's Hep C drugs, Sovaldi and Harvoni, are central to this vigorous debate, having been characterized as the "poster child for those complaining that the cost of medicines is out of control." ("Harvoni, a Hepatitis C Treatment from Gilead, Wins F.D.A. Approval," The New York Times, Oct. 10, 2014) (Compendium, Article 1).¹ It is unsurprising that Sovaldi and Harvoni would become lightning rods so quickly in the debate given the relatively prodigious Hep C patient population in the U.S. There are an estimated 2.7 to 5.2 million people in the U.S. infected with HCV. "The national dialogue [on specialty drug prices] has already started – Sovaldi's price has received public attention like no other drug in recent memory." ("How an \$84,000 Drug is Sparking a New Health-Care Debate," Washington Post, May 29, 2014) (Compendium, Article 2). That there is an intensive, indeed urgent, public debate over the excessive prices being charged for Gilead's Sovaldi and Harvoni is beyond dispute as evidenced by reference to the Compendium of attached list of articles, studies and reports, all of which touch on one or more of the following topics: the excessiveness of Gilead's HCV drug prices²; the propriety of the U.S. health care system subsidizing the availability of Gilead's Hep C drugs

¹ Plaintiffs are submitting herewith a compendium of articles that discuss Gilead's pricing practices and its impact on the U.S. health care system (the "Compendium"). The Compendium includes hyperlinks to each article referenced in Plaintiffs' Memorandum of Law, as well as additional articles that provide background information for the Court. Plaintiffs can provide a hard copy of the Compendium for the Court upon request.

² One recent study conducted by a doctor at Liverpool University in England found that sofosbuvir could be manufactured for as little as \$1 per pill. ("Gilead denied patent for hepatitis C drug sofosbuvir in India," Médecins Sans Frontières, Jan. 14, 2015) (Compendium, Article 3).

in other countries at a fraction of the U.S. prices; the relationship of price to research and development cost; the impact of Gilead’s excessive prices on patient access and on the financial sustainability of the public and private health care systems; disparate pricing between foreign and domestic markets; the selective discounting that Gilead has granted certain pharmaceutical benefits managers (“PBMS”); and the impact of excessive prices on medical provider decision-making with respect to whether and when to prescribe Gilead’s HCV drugs.

The public debate over the controversy created by Gilead’s pricing policies is not confined to the media as evidenced by:

- The Congressional investigations of Gilead’s Hepatitis C drug prices both generally and for veterans. FAC ¶¶ 8, 44.
- The unprecedented and aggressive actions taken by PBMs to negotiate lower prices from Gilead once a competitive alternative drug was introduced to the marketplace in late 2014. FAC ¶¶ 48-58.
- The SEC’s February 23, 2015 refusal to allow Gilead to exclude from its 2015 Proxy to shareholders a proposal made by the UAW Retiree Medical Benefits Trust that would compel Gilead’s management to report to shareholders on the “risks to Gilead from rising pressure to contain U.S. specialty drug prices,” including certain information about actions taken to mitigate pricing-related risks. (See discussion at Section II(E), *infra* and Exhibits 2-7, attached hereto).
- Challenges mounted in India and Europe, as well as the United States, against Gilead’s patents covering the active ingredients of its Hep C drugs. See, e.g., FAC ¶¶ 100-108.

These manifestations of governmental interest in Gilead’s pricing abuses as well as

marketplace reaction to the emergence of some competitive alternatives to Sovaldi and Harvoni confirm the unsustainable, artificially inflated prices charged for these drugs, as well as the significance of the severe problems confronting Hepatitis C patients and the health care system. But they hold little promise to succor the overwhelming dilemmas confronting the Hepatitis C population in this country given the realities of the power of the largest lobbying contingent in Washington D.C. – the pharmaceutical industry – and the lack of pricing transparency in the marketplace.

Plaintiffs are not, however, simply asking this Court to decide a public policy issue or to become embroiled in a public debate. The FAC seeks to remedy Gilead’s allegedly unlawful conduct with viable legal claims, including the recently adopted Patent Protection and Affordable Care Act of 2010 (“ACA”) as well as applicable state law. For example, and as discussed in further detail *infra*, the ACA’s anti-discrimination provisions prohibit Gilead’s pricing conduct given the unusual, if not unique, demographics of the Hepatitis C population in this country and the obvious fact that Hepatitis C is a disability. In addition, through this action, Plaintiffs seek relief for Gilead’s unjust enrichment, for breach of the duty of good faith and fair dealing in contracts to which Plaintiffs are intended third party beneficiaries, and for violations of the California Unfair Competition Law.

If nothing else, this case – and Gilead’s aggressive efforts to have it summarily dismissed – demonstrate that the American health care system is in desperate need of a fix to address the out-of-control, skyrocketing prices being extracted for Sovaldi and Harvoni. Because Plaintiffs have pled viable legal claims, Gilead’s motion to dismiss must be denied.

II. FACTUAL BACKGROUND

A. Plaintiffs' Experiences

Plaintiff Southeastern Pennsylvania Transportation Authority (“SEPTA”) commenced this action against Defendant Gilead Sciences, Inc. (“Defendant” or “Gilead”) on December 9, 2014. On January 23, 2015, SEPTA filed its First Amended Complaint (“FAC”) along with two additional Plaintiffs, Jane Doe and John Doe (collectively with SEPTA, “Plaintiffs”). *See* Docket Entry No. 8. In addition to adding these new Plaintiffs, the FAC includes a narrative of extensive factual developments and adds two claims for violations of California’s Unfair Competition Law. Pursuant to FED. R. CIV. P. 23, Plaintiffs seek to represent a class consisting of both payers (like SEPTA) that have purchased or paid for Sovaldi or Harvoni, either for themselves or for their employees or insureds, and HCV patients (like Jane and John Doe) who have been prevented from obtaining or having access to a needed Sovaldi or Harvoni regimen. *See* FAC ¶ 117.

The Plaintiff Does’ experience has been repeated across the country with lack of patient access to Gilead’s Hepatitis C drugs due to excessive prices being commonplace. A Medicaid patient profiled in a Bloomberg article on lack of access attested to the fact that cost prevented Sovaldi being available to her: “Always in the back of my head I hear the clock ticking. It is winding down faster and faster...while I wait, I just get sicker and sicker.” (“Who Gets Saved? Hepatitis Cure at \$84,000 Makes Doctors Choose,” July 23, 2014) (Compendium, Article 4). A column in the Health Affairs blog described the tensions laid bare by Sovaldi:

We are short on policy options to mitigate dilemmas such as who receives treatment and who doesn’t, whether or not cuts will be made to education and transportation funds in state and federal budgets, what other health care services we will provide less of, and where patients and payers will find the money they need to access the drug... We have the resources to pay for a fairly priced treatment, but that is of no help when the treatment is not priced fairly, and policy discussions sparked by this issue have begun to address that.

(“Sovaldi, Harvoni, and Why It’s Different This Time,” Health Affairs Blog, Nov. 21, 2014) (Compendium, Article 5).

B. Gilead’s Windfall Profits from Sovaldi and Harvoni

Sovaldi and Harvoni have both been very lucrative drugs for Gilead. Based on recent earnings reports released by the company, Sovaldi, which was approved by the FDA on December 6, 2013, accounted for over \$10.2 billion in sales in 2014 – about half of Gilead’s 2014 revenue – making it the most successful drug launch in history. By way of comparison, Gilead’s total product sales in 2013 were just over \$3 billion. Likewise, sales of Harvoni, which only began in the United States after it received FDA approval on October 10, 2014, were over \$2.1 billion for the few months that it was on the market in 2014. Approximately 94% of the sales of Sovaldi and 83% of the sales of Harvoni were made in this country. For the year ended 2014, Gilead reported \$12.1 billion in after-tax profits. As alleged in the FAC, Gilead’s senior management has also benefitted handsomely. *See* FAC ¶ 92. John Martin, Gilead’s CEO, reportedly received compensation valued at nearly \$180 million in 2013, and John Milligan, Gilead’s COO, received compensation valued at more than \$83 million in 2013. *Id.* Plaintiffs allege that these impressive sales figures and profit margins are a function of the excessive prices that Gilead commands for these drugs, as well as the significant demand from the large number of HCV infected persons who could benefit from them. FAC ¶ 6. In the United States, Gilead sells Harvoni for \$1,125 a pill, or \$94,500 for a 12-week course of treatment. *Id.* Similarly, the domestic cost of a standard 12-week regimen of Sovaldi treatment is as much as \$84,000, or \$1,000 per pill. *Id.* Gilead has yet to release 2014 management compensation data.

These domestic prices are in sharp contrast to the \$36,000 price tag that Pharmasset, the company that was acquired by Gilead after having developed and taken Sovaldi through Phase II

clinical trials, had intended to charge for a full 12 week Sovaldi regimen. FAC ¶ 8. Gilead's domestic prices for its Hepatitis C drugs are obscenely high when compared to the prices at which sofosbuvir – the active ingredient in Sovaldi and Harvoni – is being made available by Gilead in other countries. FAC ¶ 7. For example, it is estimated that the total cost of a Sovaldi treatment in Egypt is only \$900, or about 99% below the U.S. price. FAC ¶¶ 38-39. Gilead has also entered into licensing agreements to manufacture and sell generic sofosbuvir in 91 developing countries at deeply discounted prices. *Id.* Recently, Gilead's discriminatory pricing practices have gone a step further. In foreign countries, pursuant to its licensing agreements, Gilead reportedly now requires proof of citizenship and residency before a health care provider can provide access to Gilead's HCV drugs to an otherwise qualified patient. ("Indian Generic Companies Should Reject Gilead's Controversial Hepatitis C 'Anti-Diversion' Programme," Médecins Sans Frontières, Mar. 18, 2015) (Compendium, Article 6). Put simply, Gilead's conduct is designed to prevent individuals from obtaining its lifesaving HCV drugs from other countries where the price may be cheaper. Such a practice effectively bars immigrants with HCV from obtaining treatment as well as those who do not have the required papers or cannot obtain them, such as the poor. Further, Gilead requires patient-specific barcodes be placed on the HCV drug bottles that must be scanned before dispensing and also requires patients to return an empty bottle before receiving a new bottle. *Id.* Dr. Manica Balasegaram, Executive Director of Doctor's Without Borders Access Campaign, has expressed the viewpoint that such an "anti-diversion" program could potentially violate patient confidentiality and compromises treatment outcomes in order to protect Gilead's profits. *Id.*

In addition to selective discounts abroad, certain large federal agencies in the United

States, such as the Bureau of Prisons and Department of Veteran Affairs (“VA”) – and large PBMs such as Express Scripts and CVS – have also received some unspecified discounts on Sovaldi and Harvoni. *Id.* ¶¶ 41, 51-52. Indeed, since the inception of this case, a number of deals between several large PBMs and Gilead (and with other manufacturers of HCV drugs) have been announced, as reflected in the chart below:

PARTIES	DATE ANNOUNCED	CONSIDERATION FOR DISCOUNTS
Abbvie & Express Scripts	December 22, 2014	Exclusive contract to provide Abbvie’s Viekira Pak, another HCV treatment, in lieu of Sovaldi or Harvoni.
Gilead & CVS Health Corp.	January 5, 2015	Sovaldi and Harvoni to be exclusive HCV treatments for most covered patients.
Gilead & Anthem	January 8, 2015	Harvoni to be “primary” option for HCV patients.
Gilead/AbbVie & Prime Therapeutics LLC	January 12, 2015	Both Harvoni and Viekira Pak to be offered.
Gilead & AETNA	January 16, 2015	Gilead’s HCV drugs to be “preferred” treatments.
Gilead & Humana	January 16, 2015	Harvoni and Sovaldi to be the “exclusive” HCV treatment for patients seeking treatment.
Gilead & EnvisionRX	January 26, 2015	Sovaldi and Harvoni to be provided to customers on an “exclusive” basis.
Gilead & United Health Care	January 28, 2015	Harvoni to be the “preferred” HCV treatment for commercial, fully-insured customers using Optum RX
Gilead & Harvard Pilgrim	January 29, 2015	Harvoni to be on “preferred” coverage list for members who have Genotype 1, advanced liver scarring or cirrhosis.
Gilead & Catamaran	February 3, 2015	Harvoni and Sovaldi to be “exclusive” HCV treatment.

See id. ¶¶ 48-68.

These “discounts” are really a misnomer since they are adjustments to the HCV drugs’ hyper-inflated price starting point. Moreover, the discounts are contained in exclusivity contracts that are limited in their impact and provide no transparency with respect to pricing or related

terms and conditions. Indeed, Gilead’s ready willingness to “discount” its obscene prices is irrefutable evidence that its 2014 prices for Sovaldi and Harvoni were a fiction. In addition, selective discounting does nothing to remedy the excessive charges already imposed by Gilead on the health care system or to benefit anyone who is not eligible for the “discount.” Indeed, even some of the entities already receiving significant discounts have signaled that those prices are unsustainable: the VA, which is the largest single purchaser of HCV drugs in the United States, and which already pays a discounted price of \$539 per pill for Sovaldi, has recently asked Congress for an additional \$1.3 billion to purchase Sovaldi and other HCV treatments. FAC ¶¶ 42-43. As Jeff Myers, the chief executive officer for Medicaid Health Plans of America, has observed “unfortunately the prices we’re starting from are at such a ridiculously high level because of the pharmaceutical companies’ pricing model that states still will find it difficult to manage these treatment costs.” FAC ¶ 52.

C. The Effects of Gilead’s Pricing Practices

Gilead’s pricing practices are under investigation and/or have been called into question by both the Senate Finance Committee and the Senate Committee on Veterans’ Affairs. FAC ¶¶ 8, 44-46. The Senate Finance Committee has specifically questioned whether the market for Sovaldi “is working efficiently and rationally,” and whether “payors of health care....can carry such a load.” *Id.* ¶ 8. And during a recent Veterans’ Affairs hearing, one senator likened Gilead’s conduct to gouging American consumers and taxpayers, as well as ignoring a moral obligation to help sick people gain access to these needed drugs. *Id.* ¶ 45. Numerous members of the medical community have also publicly decried Gilead’s unprecedented exploitation of these much-needed drugs, and have analogized the situation as akin to paying for clean water after Hurricane Katrina; described these prices as “intolerably high” “public extortion” and “unsustainable”; stated that

they “put public and private payers in this country over a barrel”; and said that it “forces patients to decide between medications and other staples like food or rent” and “forces payers – small and large businesses, health plans, government agencies and others, to consider whether or not they can even sustain the pharmacy benefit they provide to members.” *See id.* ¶ 4, 9, 14, 50. The president of a major group of insurers has publicly stated that multiplying Sovaldi’s price tag by the number of HCV affected persons “can torpedo the whole health insurance system.” *Id.* ¶ 66. As a result, Gilead’s pricing has left some states, insurers and Medicaid programs with no other choice but to limit access to the drugs to only the sickest of patients, and/or those who can satisfy a litany of eligibility criteria. *Id.* ¶ 62. Many in the medical field fear that the cost for Sovaldi and Harvoni will change diagnosis decisions from what care is best for the patient to what cost can the health care system bear – a concept known as “rationing care” in the medical community.

While Gilead maintains certain “Patient Assistance” programs that purport to make its high-priced HCV drugs available to patients who cannot afford them, the reality is that the vast majority of patients without the financial means or insurance coverage to access Sovaldi or Harvoni have not been able to utilize Gilead’s programs. FAC ¶ 10. The complaint cites a recent conference where a panelist remarked that she was forced to sell her home in order to pay for her Hepatitis C treatment (this after a Gilead representative on the same panel had stated that “access” to its drugs was “not the problem.”). Similarly, Plaintiff Jane Doe was unable to access Sovaldi through Gilead’s assistance program. *Id.* ¶ 21. In practice, these “Patient Assistance” programs are filled with hurdles, such as burdensome financial and medical records requirements and lengthy wait telephone hold times. FAC ¶¶ 75-76.

Gilead’s pricing scheme has had a disproportionately adverse impact on racial minorities and those in lower income brackets (demographics that have had a historically higher incidence

of Hepatitis C infections). FAC ¶ 12. The FAC cites a study which indicates that “[n]on-Hispanic Blacks have the highest prevalence of HCV infection in the United States, about twice that reported among non-Hispanic Whites.” FAC ¶ 133. Moreover, HCV prevalence is substantially higher among prison inmate populations, of which African Americans make up approximately 44.3%. For this and other reasons discussed in the FAC, Gilead’s pricing has had a disparate impact on the ability of minorities to access Sovaldi and Harvoni. *Id.*

D. Gilead’s Patent Protection is Vulnerable

While Gilead purports to have patent protections that cover its sale of sofosbuvir, this is the subject of ongoing infringement disputes with competitors and other groups, in both United States courts and foreign tribunals. *See* FAC ¶¶ 99-116. For example, Gilead’s patent application for Sovaldi was recently rejected in India because its Patent Office determined that Sovaldi’s active ingredient was only a “molecule with minor changes” from a previous compound developed by another company, and thus undeserving of patent protection.³ Separately, on February 10, 2015, it was announced that a legal challenge to Gilead’s Sovaldi patent was commenced by a medical-aid charity in the European Patent Office.⁴ It has been reported that the basis for this action is that Gilead is utilizing its intellectual property rights to charge “unsustainable” prices.⁵ Regardless of the ultimate outcome of these patent disputes and challenges, Gilead is not authorized by the limited rights afforded to it by the patent laws in the United States to abuse its purported monopoly on Sovaldi or Harvoni by charging discriminatory and exorbitant prices under the circumstances of this case.

³ This decision by India’s Patent Office reportedly has since been remanded by the Delhi High Court on the basis that it failed to follow procedures in evaluating Gilead’s patent application.

⁴ *See* (“Gilead’s Hepatitis C Drug Patent Challenged by Medical Charity,” Bloomberg, Feb. 10, 2015) (Compendium, Article 7).

⁵ *Id.*

Aside from its patents, the rationales offered by Gilead to justify its exorbitant pricing of Sovaldi and Harvoni are defied by both logic and the real world facts. Gilead's brief attempts to justify these prices by citing to its costly and purportedly risky investment to acquire sofosbuvir, and by noting the efficacy and high demand for these drugs. *See* Def. Mem. at 2-3. If this were an acceptable way to set the price of new life-saving drugs, then virtually no drug – including the polio vaccinations and penicillin – would be affordable when first developed and marketed. *See* FAC ¶ 96. While Gilead is correct that it paid \$11 billion to acquire Pharmasset and obtain sofosbuvir, it does not dispute Plaintiffs' allegations that it is earning roughly \$200 million per week from Sovaldi sales alone – thus putting it on track to recover this entire merger consideration with roughly one year's worth of revenue from Sovaldi sales.⁶ *See* FAC ¶¶ 8, 30. Moreover, its pricing of drugs that could benefit many millions of people affected by the HCV epidemic at levels reserved for orphan drugs is diametrically at odds with the regulatory framework for the pricing of such drugs in the United States – under which high prices may sometimes be justified in light of a very small patient population. *Id.* ¶¶ 79-88. That is not the case here.

The reality of this situation is obvious: Gilead is taking full advantage of its purported patent rights by charging the highest possible prices for Sovaldi and Harvoni for as long as it can. This abusive and discriminatory conduct cannot be justified by the patent laws or otherwise in light of the extraordinary and unique facts of this case. To allow Gilead's behavior to continue unchecked will effectively deprive millions of Americans from obtaining these much needed

⁶ Gilead's brief also does not contest the data cited in the FAC demonstrating that the actual number of liver transplants performed in the U.S. due to HCV – a purported cost-saving metric on which it has previously relied in public attempts to justify these exorbitant prices – are, in fact, exceedingly rare. See FAC ¶¶ 97-98.

drugs, and will allow it to retain billions of dollars in excess of anything that could be considered a reasonable profit, at the expense of the health care system.⁷ Indeed, as the medical community has already observed, Gilead intends to “squeeze every last drop of profit” out of its HCV drugs and will continue limiting access to its lifesaving drugs to do so.⁸

E. Gilead’s Conduct Implicates Significant Social Policy

Gilead’s conduct implicates some of the most compelling and confounding social issues that this nation confronts in the delivery of one of the most essential elements of human existence: health care. And this is not some pedestrian aspect of health care; it is the difference between life and death, disabled vs. not disabled, miserable vs. quality existence. Gilead’s conduct directly implicates some of the most nettlesome and morally-challenging social issues confronting the health care industry: which patients shall have access to a miracle cure; can and should the American taxpayer, through both the public and private health care system, underwrite widespread access to Gilead’s drugs being sold at excessive prices; whether rationing of miracle cures is morally acceptable; whether extortionist conduct by corporate entities can be tolerated in our society; and whether corporate management is subject to any limits governing its greed and personal and institutional aggrandizement.

Gilead’s own shareholders have expressed serious concerns about these seminal social issues. On November 14, 2014, the UAW Retiree Medical Benefits Trust (“UAW Trust”) proffered the following shareholder proposal to be included in Gilead’s Proxy Statement for the 2015 Annual Meeting of Stockholders:

⁷ Gilead does not contest the data cited in the FAC demonstrating that the actual number of liver transplants performed in the U.S. due to HCV – a purported cost-saving metric on which it has previously relied in public attempts to justify these exorbitant prices – are, in fact, exceedingly rare.

⁸ See Compendium, Article 6.

RESOLVED, that shareholders of Gilead Sciences (“Gilead”) ask the Board of Directors to report to shareholders by December 31, 2015, at reasonable cost and omitting confidential or proprietary information, on the risks to Gilead from rising pressure to contain U.S. specialty drug prices. Specialty drugs, as defined by the Center for Medicare and Medicaid Services, are those that cost more than \$600 per month. The report should address Gilead’s response, if any, to risks created by:

- The relationship between Gilead’s specialty drug prices and each of clinical benefit, patient access, the efficacy and price of alternative therapies, drug development costs and the proportion of those costs borne by academic institutions or the government;
- Price disparities between the U.S. and other countries and public concern that U.S. patients and payers are shouldering an excessive proportion of the cost burden;
- Price sensitivity of prescribers, payers and patients; and
- The possibility that pharmacoconomics techniques such as cost-effectiveness studies will be relied on more by payers in making specialty drug reimbursement decisions.

See Exhibit 2. In support of its proposal, UAW Trust cited the “vigorous national debate...

spurred by the launch of Gilead’s Hepatitis C drug Sovaldi, regarding appropriate pricing of specialty drugs and the impact of specialty drug costs on patient access and the health care system.” Its supporting statement further cited:

- a. “Sovaldi’s \$84,000 price tag has led to scrutiny from payers and legislators and a barrage of negative media attention.”
- b. Concern “that the high priced Sovaldi (and combination drug Harvoni which includes Sovaldi) exposes Gilead to financial and reputational risks.”
- c. “Sovaldi’s price has led payers to restrict patient access.”
- d. “Sovaldi has focused Congress’ attention on drug pricing.”

Id. Gilead sought to exclude the UAW Trust’s proposal from the 2015 proxy statement, informing the SEC in a letter dated December 8, 2014 (Exhibit 3) that (a) the subject matter of the proposal constitutes tasks that “are so fundamental to management’s ability to run a company on a day-to-day basis that they could not, as a practical matter, be subject to shareholder oversight” and (b) “the degree to which the proposal seeks to ‘micro-manage’ the company by probing too deeply into matters of a complex nature upon which shareholders, as a group, would

not be in a position to make an informed judgment.” *Id.* at 3 (quoting SEC Release No. 34-40018 (May 21, 1998)) (“1998 Release”)).

The UAW Trust responded to Gilead’s December 8 letter, in a letter to the SEC dated January 7, 2015 (Exhibit 4), contending that its proposal did not implicate “ordinary business,” but rather was focused “on sufficiently significant social policy issues” thereby precluding the omission of its proposal from the proxy statement. *Id.* at p.2 (quoting from the 1998 Release). Gilead contested the UAW Trust’s assertions and in a letter to the SEC dated January 14, 2015 (Exhibit 5), sought to trivialize the proposal, asserting that the proposal “does not relate to a significant policy issue” and, further, even if a significant policy issue was implicated, “it involves matters of ordinary business prices charged by the Company for certain of its products.” *Id.* at p.2. Gilead essentially was taking the position that “mere pricing” of its Hepatitis C products could not trigger a significant policy issue. The UAW Trust responded that given the circumstances surrounding the public outcry and controversy over the implications of the pricing of Sovaldi and Harvoni, “pricing is the significant social policy issue.” (UAW Trust’s January 22, 2015 letter to the SEC, attached as Exhibit 6, at p.5, emphasis in original).

On February 23, 2015, the SEC Office of Chief Counsel, Division of Corporation Finance, determined that the UAW Trust’s proposal must be included on the 2015 proxy:

We are unable to concur in your view that Gilead may exclude the proposal under rule 14a-8(i)(7). In our view, the proposal focuses on Gilead’s fundamental business strategy with respect to its pricing policies for pharmaceutical products and does not seek to micromanage the company to such a degree that exclusion of the proposal would be appropriate. Accordingly, we do not believe that Gilead may omit the proposal from its proxy materials in reliance on rule 14a-8(i)(7).

Exhibit 7. Regardless of how Gilead’s shareholders ultimately vote on this proposal, the foregoing exchange makes clear that these pricing issues cannot be shielded from scrutiny on the basis that doing so would interfere with (or “micro-manage”) the day-to-day management of the

company. Under the circumstances of this case, the exorbitant prices set by Gilead for the sale of its HCV drugs in this country have raised significant public policy and legal issues that go well beyond the routine matter of a company setting the price for products it sells.

III. STANDARD OF REVIEW

Gilead seeks to have Plaintiffs' complaint dismissed pursuant to FED. R. CIV. P. 12(b)(6) for failure to state a claim. *See* Def. Mem. at 5. In order for a plaintiff to survive such a motion, “a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *McBride v. Warden of the Allegheny County Jail*, 577 Fed. Appx. 98, 99 (3d Cir. 2014) (quoting *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009)). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.”” *Thakar v. Tan*, 372 Fed. Appx. 325, 328 (3d Cir. 2010) (quoting *Ashcroft*, 129 S. Ct. at 1949). This Court has stated that “in evaluating a pleading’s sufficiency in relation to a Rule 12(b)(6) motion to dismiss, a ‘District Court must accept all of [a pleading's] well-pleaded facts as true’ and draw all reasonable inferences therefrom in the light most favorable to the plaintiff, ‘but may disregard any legal conclusions[,]’ in determining whether the plaintiff has a ‘plausible claim for relief.’” *Leonard v. Bristol Twp. Sch. Dist.*, No. 09-4692, 2010 U.S. Dist. LEXIS 76187, at *6-7 (E.D. Pa. July 28, 2010) (quoting *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210-11 (3d Cir. 2009)). A plaintiff “must only allege facts that ‘raise a reasonable expectation that discovery will reveal evidence’ that substantiates his claim.”” *Rumble v. Fairview Health Servs.*, No. 14-2037, 2015 U.S. Dist. LEXIS 31591, at *39 (D. Minn. Mar. 16, 2015) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)).

While Gilead asks this Court to dismiss the complaint in its entirety with prejudice, *see*

Def. Mem. at 5-6, the Third Circuit has “held that even when a plaintiff does not seek leave to amend, if a complaint is vulnerable to 12(b)(6) dismissal, a District Court must permit a curative amendment, unless an amendment would be inequitable or futile.”” *In re N.J. Title Ins. Litig.*, 683 F.3d 451, 462 (3d Cir. 2012) (quoting *Alston v. Parker*, 363 F.3d 229, 235 (3d Cir. 2004)); *Jackson v. Phila. Hous. Auth.*, No. 13-4872, 2014 U.S. Dist. LEXIS 36545, at *19-20 (E.D. Pa. Mar. 20, 2014)).

IV. ARGUMENT

A. Plaintiffs’ ACA Claim Should Not Be Dismissed.

Gilead first seeks dismissal of Plaintiffs’ claim for violations of the ACA. *See* Def. Mem. at 6-11. The ACA prohibits three types of conduct: (i) discrimination, (ii) the denial of benefits, and (iii) the exclusion from participation in certain health programs and activities on the basis of, *inter alia*, race, color, or disability. Specifically, the statute provides in pertinent part:

... an individual shall not, on the ground prohibited under title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), ... or section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance...

42 U.S.C. § 18116(a).⁹

Preliminarily, three things are noteworthy about Gilead’s motion with respect to the ACA claim. First, Gilead correctly notes that the Civil Rights Act of 1964 can form one of the grounds upon which the ACA’s antidiscrimination prong can be premised. *See* Def. Mem. at 6. But its brief fails to respond to the allegations in the FAC which detail why and how the Civil Rights Act is implicated here (*see* FAC ¶ 133). That, in itself, should result in the denial of its motion with

⁹ Plaintiffs have alleged, and Gilead does not dispute, that it has received “Federal financial assistance” sufficient to qualify it as an organization subject to the ACA, the Rehabilitation Act and the Civil Rights Act. *See* FAC ¶ 134.

respect to this claim. Second, Gilead does not argue that the ACA claim is preempted by the patent laws, as it does with respect to the state law claims. *See* Def. Mem. at 12-14. And third, Gilead's brief completely ignores case law interpreting the relatively new ACA in the substantially similar context of the denial of benefits and the charging of prices only to patients with a disability.

As discussed below, the FAC sets forth two independent grounds upon which the ACA provision is applicable. First, Gilead has discriminated against the Doe Plaintiffs and other similarly situated persons suffering from a disability (*i.e.* Hepatitis C) in violation of section 504 of the Rehabilitation Act. *See* FAC ¶ 132. Second, under the circumstances here, Gilead's conduct and pricing practices have had a disparate impact on minorities protected by the Civil Rights Act of 1964. *Id.* ¶ 133. As discussed below, the grounds upon which Gilead seeks to have these claims dismissed (to the extent it even addresses them) are unpersuasive.

1. Violation of the ACA Based on the Rehabilitation Act.

The Supreme Court has stated that “[t]he Rehabilitation Act of 1973 establishes a comprehensive federal program aimed at improving the lot of the handicapped.” *Mary Jo C. v. N.Y. State & Local Ret. Sys.*, 707 F.3d 144, 157 (2d Cir. 2013) (quoting *Consolidated Rail v. Darrone*, 465 U.S. 624, 626 (1984)). The purpose of the statute’s antidiscrimination provision – section 504 – is “to permit handicapped individuals to live life as fully as they are able...” *Poole v. South Plainfield Bd. of Education*, 490 F. Supp. 948, 953-54 (D.N.J. 1980). To state a claim for a violation of section 504 of the Rehabilitation Act, a plaintiff “must demonstrate that: (1) she is a qualified individual with a disability; (2) she was denied the benefits of a program or activity of a public entity which receives federal funds; and (3) she was discriminated against based on her disability.” *Reed v. Schuylkill Health Sys.*, No. 13-1175, 2013 U.S. Dist. LEXIS

172907, at *8-9 (M.D. Pa. Dec. 9, 2013) (quoting *Calloway v. Boro of Glassboro Dep't of Police*, 89 F. Supp. 2d 543, 551 (D.N.J. 2000)). Section 504 “is limited to entities that actually receive federal financial assistance because Congress sought to impose the act's coverage ‘as a form of contractual cost of the recipient's agreement to accept the federal funds.’” *Shepherd v. United States Olympic Comm.*, 94 F. Supp. 2d 1136, 1146 (D. Colo. 2000) (quoting *United States Dep't of Transp. v. Paralyzed Veterans of America*, 477 U.S. 597, 605 (1986)).¹⁰ As noted above, Gilead does not contest the federal funding element of this claim.

a. Gilead’s Discriminatory Pricing Directed Towards HCV-Positive Persons Violates the ACA.

Without citing a single case, Gilead states that Plaintiffs do not plead that it is actually discriminating with respect to price because the FAC does not allege that “Gilead offers its HCV treatments at lower prices to consumers *who do not have HCV*.” Def. Mem. at 7 (emphasis in original). This argument is absurd on its face; as Gilead itself acknowledges, “consumers who are not suffering from HCV do not seek to buy HCV treatments in the first place.” *Id.* at 1-2. The real issue Gilead should posit is whether Section 504 of the Rehabilitation Act is violated if:

1. HCV victims in the United States are charged exorbitant prices for Gilead’s HCV drugs as compared to the prices charged HCV patients abroad?
2. HCV victims in the United States are being charged significantly higher prices for Gilead’s Hep C drugs compared to other domestic HCV victims who, by happenstance, are part of health plans or programs that have entered into agreements that make these drugs available at a discounted price?

¹⁰ The Third Circuit has recently clarified that compensatory damages can be recovered for a section 504 claim upon a showing of “deliberate indifference.” *S.H. v. Lower Merion Sch. Dist.*, 729 F.3d 248, 262 (3d Cir. 2013). Deliberate indifference generally encompasses (1) knowledge that harm to a federally protected right is substantially likely and (2) failure to act upon that likelihood. *Id.* at 263 (citations omitted).

3. HCV victims are being denied access to Gilead's Hep C drugs because their health plans or programs refuse or limit access due to the exorbitant prices charged by Gilead?
4. HCV victims in the United States are denied access to Gilead's HCV drugs due to Gilead's excessive and discriminatory pricing practices, contracts and policies?

Answering these questions requires additional sub-inquiries. First, is an HCV victim suffering from a "disability"? Second, is Gilead's price discrimination prohibited under Section 504? As set forth below, the answer to both of these questions is yes.

b. The Doe Plaintiffs and Other Hepatitis C Infected Persons Have a "Disability" Within the Meaning of the Rehabilitation Act and the ACA.

The very first paragraph of Gilead's brief states that Sovaldi and Harvoni are "life-saving drugs" that can cure HCV, "a devastating and sometimes fatal disease..." Def. Mem. at 1. Yet, in seeking to dodge liability for Plaintiffs' ACA claim, Gilead argues that "simply having HCV is not a disability." *Id.* at 7. While Gilead is correct that an impairment qualifies as a "disability" for purposes of the Rehabilitation Act only if it "substantially interferes with at least one major life activity," *id.* at 10, its contention that HCV does not meet this criterion is wholly unpersuasive.

The FAC unambiguously alleges that HCV interferes with numerous life activities, including caring for oneself, performing manual tasks, reproducing/procreating, engaging in sexual relations, and working.¹¹ FAC ¶ 132. The Declaration of Plaintiff John Doe, submitted herewith as Exhibit 8, further confirms that his HCV has substantially interfered with numerous

¹¹ Gilead clings to the FAC's allegation that there are many Americans with HCV who are unaware that they have it (FAC ¶ 24). *See* Def. Mem. at 10-11. The fact that there are HCV victims who, based on the early stage of their disease, are unaware of it has no bearing on its motion to dismiss the claims of Plaintiffs Jane and John Doe, who mirror the condition of millions of individuals in this country who know they are suffering from HCV and are disabled by the disease. FAC ¶¶ 21-22.

of his major life activities. Gilead's brief ignores Supreme Court precedent that has held, in a substantially identical context, that someone infected with HIV is substantially limited in participating in the major life activities of reproduction and sex. *See Bragdon v. Abbott*, 524 U.S. 624, 639 (1998).¹² Consistent with this case, "most courts have found plaintiffs with Hepatitis C to be 'disabled' within the meaning of the ADA or the Rehabilitation Act." *Powell v. City of Pittsfield*, 221 F. Supp. 2d 119, 146-147 (D. Mass. 2002) (citing *Quick v. Tripp, Scott, Conklin & Smith, P.A.*, 43 F. Supp. 2d 1357, 1368 (S.D. Fla. 1999) (holding that *Bragdon* "compels the conclusion that [plaintiff's] assertion that the significant limitations placed on her major life activity of reproduction due to the hepatitis C virus, qualifies as a recognized ADA disability.")); *White v. Bank of America Corp.*, No. 99-2329, 2000 U.S. Dist. LEXIS 16111, at *4 (N.D. Tex. Nov. 2, 2000) (holding that plaintiff's hepatitis C was disability because "here, as in *Bragdon*, if [plaintiff] attempts to conceive a child, he may infect his partner with the virus."); *Rollf v. Interim Personnel, Inc.*, No. 99-44, 1999 U.S. Dist. LEXIS 18096, at *3-4 (E.D. Mo. Nov. 4, 1999) (holding that plaintiff survived motion to dismiss since he was substantially limited in major life activity of reproduction, and finding "if he were to attempt to conceive a child, he would impose a significant risk of infection on the woman with whom he attempted such conception, because hepatitis C is transmitted through blood transfusions and sexual intercourse.")). In *Powell, supra*, Judge Michael A. Ponso held that the plaintiff's hepatitis C infection "substantially limited" a "major life activity" because "[t]he medical evidence...showed that hepatitis C causes cirrhosis, liver failure, cancer, and death" and, therefore, if the plaintiff "engaged in sexual relations with his wife for purposes of reproduction or marital intimacy, he ran a risk of infecting her with a

¹² Notably, in a subsequent case to reach the Supreme Court only four years after *Bragdon*, the defendant conceded that a party infected with hepatitis C had a "disability." *Chevron U.S.A., Inc. v. Echazabal*, 122 S. Ct. 2045, 2048 n.2 (2002).

deadly disease.” *Id.* at 147. This Court should reach the same conclusion here.¹³

Gilead’s reliance on *Ellis v. Mohenis Services, Inc.*, No. 96-6307, 1998 U.S. Dist. LEXIS 13219 (E.D. Pa. Aug. 24, 1998) and *Amos v. Correctional Medical Services, Inc.*, No. 06-1892, 2009 U.S. Dist. LEXIS 55378 (D.N.J. Jun. 30, 2009) is misplaced. *See* Def. Mem. at 11. Aside from the fact that both decisions arose in the context of a motion for summary judgment, the underlying record in these cases is materially different. The plaintiff in *Ellis* – who sued his employer under the ADA – contended that his HCV infection substantially limited the major life activity of working, but he apparently conceded that he could still work 40 hours per week, and failed to put forth any evidence that he was unable to work at any other job other than his current one.¹⁴ *Ellis*, 1998 U.S. Dist. LEXIS 13219, at *9-10. The plaintiff in *Amos* was a prisoner who was treated for and “effectively cured” of HCV while he was incarcerated. 2009 U.S. LEXIS 55378, at *7, *15. In support of his claim that the prison failed to timely diagnose and treat his condition, he relied on an expert’s report that contained “two complete misstatements of fact.” *Id.* at *10-11. With respect to the defendants’ contention that the plaintiff’s prior HCV status was not a “disability” within the meaning of the ADA, the court held that the plaintiff had “made absolutely no such showing,” and, in fact, “has not even opposed the Motion for Summary Judgment on this count.” *Id.* at *18. Neither of these decisions provide a basis for the Court to

¹³ At a minimum, the Court should deny Gilead’s FED. R. CIV. P. 12(b)(6) motion to dismiss as premature. As the discussion of these cases suggest, determining whether a particular virus or condition “substantially interferes with at least one major life activity” can be a factually intensive analysis that is not appropriate to be resolved in connection with a motion to dismiss. *See Homeyer v. Stanley Tulchin Assocs.*, 91 F.3d 959, 962 (7th Cir. 1996) (“...we find premature the district court’s conclusion that Homeyer cannot establish that her major life function of working is substantially limited.... this conclusion is a factual determination, and is therefore not the type of finding that is generally appropriately made on a motion to dismiss. ”).

¹⁴ That was significant, the Court noted, because “[t]he inability to perform a single, particular job does not constitute a substantial limitation in the major life activity of working.” *Id.* at *9 (citing 29 C.F.R. § 1630.2(j)(3)(i)).

dismiss this claim for lack of a qualifying “disability.”¹⁵ And unlike in these cases, the Jane and John Doe Plaintiffs here are not simply people who have HCV – they are people infected with a condition that will only get progressively worse because they cannot obtain Harvoni or Sovaldi as a result of Gilead’s alleged wrongful conduct.

There is more: Gilead’s top executives have made numerous public remarks about the horrible symptoms and prognosis faced by people infected with hepatitis C. For example, CEO John Martin told *Fortune* magazine that “Typically only a few people can be treated, and only a few cured. It’s a virus that causes liver failure and cancer. It’s insidious. It replicates in the body for a long time.”¹⁶ Likewise, John Milligan, Gilead’s President and Chief Operating Officer called it “a horrible disease.”¹⁷ Mr. Milligan also reportedly said “we forget that HCV is a terrible disease” during the September 9, 2014 Morgan Stanley Healthcare Conference. More recently, the U.K. and Ireland general manager of Gilead made the following comments in response to the National Institute for Health and Clinical Excellence’s decision to delay widespread approval of Sovaldi until it can obtain sufficient funding to cover its hefty price:

While we are pleased that NICE has recognized the clinical and economic value of treatment with sofosbuvir, we are concerned that the majority of patients will not gain access to this important medicine until later this year,...Patients with cirrhosis would be the most likely to suffer irreversible consequences as a result of a delay to treatment. In the UK, for every month hepatitis C patients with cirrhosis continue untreated, approximately 40 will develop a preventable cancer that is likely to be incurable and 30 patients will unnecessarily progress to decompensation that could have been prevented by treatment.¹⁸

¹⁵ Plaintiffs do not address the Third Circuit’s unpublished opinion in *Shultz v. Potter*, 142 F. App’x 598 (3d Cir. 2005) other than to note that the case involved diabetes, and the word “hepatitis” does not appear anywhere in the opinion.

¹⁶ (“John Martin: Gilead’s Disease Hunter,” *Fortune*, May 16, 2011) (Compendium, Article 8).

¹⁷ (“Gilead Hepatitis C Drug Sovaldi Racks Up \$3.5 bln in quarter,” *Reuters*, July 23, 2014) (Compendium, Article 9).

¹⁸ (“Gilead Frustrated Despite Final NICE Sovaldi Nod,” *Pharma File*, February 15, 2015)

For Gilead to now profess a position directly contrary to these previous statements by its officers and managers solely to serve its own interests in this litigation is disingenuous at best. Its motion to dismiss on this basis should be denied.

c. Price Discrimination Violates Section 504.

While there is scant case law interpreting the recently enacted ACA, one of the few opinions that has addressed it supports the view that price discrimination violates Section 504. *East v. Blue Cross and Blue Shield of La.*, No. 14-115, 2014 U.S. Dist. LEXIS 23916 (M.D. La. Feb. 24, 2014). That case – which is noticeably absent from Gilead’s brief – involved a challenge by an HIV-positive plaintiff to an announcement by his health insurer that it would stop accepting federal Ryan White Funds, which are designed to provide assistance for low income people living with HIV. *Id.* at *1-2. This change had the effect of significantly driving up the costs of health insurance for those members who were HIV-positive to the point where they could no longer afford coverage or these needed drugs. *Id.*

The plaintiff sought – and the district court issued – a Temporary Restraining Order to prevent Blue Cross from implementing this change on the grounds that, among other things, it violated the anti-discrimination provision of the ACA. *East*, 2014 U.S. Dist. LEXIS 23916, at *2. In finding that the plaintiff had satisfied the “substantive requirements” for obtaining a TRO, the district court summarized his allegations as follows:

[plaintiff] is ‘an individual living with HIV’;

he ‘take[s] two medications [each day] to treat [his] HIV,’;

his insurance provider, Blue Cross, has heretofore accepted full payment for his insurance premiums from ‘the Louisiana Health Insurance Program which receives funding from the Ryan White Program,’;

(Compendium, Article 10). Of course, the only reason for this delay is due to the exorbitant prices at which Gilead is selling its Hepatitis C drugs.

[plaintiff] is otherwise unable to pay his monthly insurance premium of \$1,306; Blue Cross and the other named Defendants—Vantage and Louisiana Health—recently decided ‘that they will no longer be accepting Ryan White assistance payments for health insurance premiums,’; this decision has caused East to miss his most recent payment, which means that he is ‘now without insurance coverage,’; East does not otherwise qualify for health care assistance; and, finally, lacking insurance, East will “run out of . . . essential medication,” which will, eventually, result in his death.

Id. at *5 (emphasis supplied; internal citations omitted). The district court then held that these allegations were sufficient to establish a “substantial likelihood of success” on the merits of the plaintiff’s ACA claim:

[plaintiff] has made a preliminary showing that he is likely to succeed on the merits of his claim because the Affordable Health Care Act contains an express Nondiscrimination provision, requiring that ‘an individual shall not . . . be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance,’

Id. at *6-8, n.1 (quoting 42 U.S.C. § 18116).¹⁹

The district court’s decision in *East* stands for the proposition that an ACA claim can be premised on pricing practices that effectively deprive people with a disability from obtaining their much needed prescription medicine. Moreover, it demonstrates that the ACA is not limited to just price discrimination. As discussed in more detail below, the statute also proscribes the “exclus[ion] of participation” and the “deni[al] [of] benefits” from any covered health program (a proposition not disputed by Gilead). *See* 42 U.S.C. § 18116(a). Gilead cannot credibly contend that the sticker prices it has charged for Sovaldi and Harvoni have not excluded or

¹⁹ After the issuance of this TRO, the plaintiff indicated that he “has obtained all the prospective relief he requested,” and voluntarily dismissed the case without prejudice.

denied the ability of HCV patients (like Plaintiffs Jane and John Doe) from obtaining these drugs. *See* FAC ¶¶ 21-22 (alleging that the Doe Plaintiffs were unable to access these drugs due to their excessive prices). As such, its argument that this claim should be dismissed is unpersuasive.

Gilead's position is further undermined by another recent opinion interpreting this same ACA provision. *Rumble v. Fairview Health Serv.*, No. 14-2037, 2015 U.S. Dist. LEXIS 31591 (D. Minn. Mar. 16, 2015). The plaintiff in that case alleged that a hospital provided him with "worse care" because of his status as a transgender man. *Id.* at *2. Specifically, the plaintiff cited to instances where an emergency room doctor treated him "with hostility and aggression while asking him pointed questions [related to his protected gender identity status] that were allegedly meant to embarrass [plaintiff]." *Id.* at *42. The plaintiff claimed that this conduct – which cumulated in the doctor abruptly terminating his examination without making any diagnosis – violated section 1557 of the ACA.²⁰ *Id.* at *12, *18.

In denying the defendants' motion to dismiss this claim, the court stated that it was "the first case that requires interpretation of Section 1557 [of the ACA]," which it described as a statute through which "Congress intended to create a new, health-specific, anti-discrimination cause of action...." *Rumble*, 2015 U.S. Dist. LEXIS 31591, at *25, *29. In applying the statute to these facts, the court discussed the three different categories of conduct that can violate the ACA:

According to Section 1557, a covered entity...may not exclude an individual from being a patient in the hospital, deny the individual the benefits of being a patient, or subject the individual to discrimination, on the basis of sex. See 42 U.S.C. §

²⁰ This is a class protected from discrimination under Title IX of the Education Amendments of 1972 which, along with the Rehabilitation Act of 1973, Civil Rights Act of 1964, and Age Discrimination Act of 1975, is one of the civil rights statutes that is referenced and incorporated into the ACA. *See Rumble*, 2015 U.S. Dist. LEXIS 31591, at *18-20, *25. The *Rumble* court read "Section 1557 as referencing these four statutes to list 'the ground[s]' on which discrimination is prohibited in a health care setting." *Id.* at *26. Further it concluded that "Section 1557 provides Plaintiff with a private right of action to sue Defendants" and that the "enforcement mechanisms available under those four statutes apply to violations of Section 1557." *Id.* at *18, n.3, *19.

18116. Therefore, in order for [the emergency room doctor's] action to rise to an actionable level, he must have either excluded Rumble from receiving medical care at the hospital, denied Rumble the benefits of medical care at the hospital, or otherwise discriminated against him. See *id.* The Court finds that Plaintiff alleges facts sufficiently demonstrating that [the emergency room doctor] discriminated against Rumble, and denied Rumble the benefits of medical care that he was entitled to as a patient in the emergency room at Fairview Southdale Hospital.

Id. at *42.

The court further explained that, when “[r]ead as a whole,” the doctor’s alleged mistreatment of the plaintiff on the basis of a protected class “rises to the level of the denial of benefits of appropriate medical care” in violation of the ACA. *Rumble*, 2015 U.S. Dist. LEXIS 31591, at *44. Notably, the court also rejected the defendants’ argument that this discriminatory conduct was immaterial for purposes of the ACA because the plaintiff was eventually admitted to the hospital after this mistreatment by the emergency room doctor: “Section 1557 does not require the plaintiff to demonstrate that he received no medical care or attention. Rather, the statute simply requires that the plaintiff demonstrate that he was denied the benefits of a health program or activity, or discriminated against. Here, Plaintiff meets this burden.” *Id.* at *45 (emphasis added).

Plaintiffs here likewise meet this burden. Just like the emergency room doctor in *Rumble*, Gilead’s alleged conduct has had the effect of excluding Plaintiffs from receiving needed medicine, denying them the benefits thereof, and discriminating against them on account of their protected HCV status. Consistent with that case, Gilead’s motion to dismiss this claim should be denied.

d. Gilead’s “Neutral Price” Argument Misses the Mark.

i. Absence of a “neutral” price dooms Gilead’s argument.

The section of Gilead’s brief entitled “A Neutral Price is Not Discriminatory” (Def. Mem. at 8-10) is remarkable because nowhere in that section – or in the remainder of its brief – does Gilead assert or hint at a “neutral” price charged by it for its HCV drugs. This is unsurprising in light of the allegations contained in the FAC (FAC ¶¶ 38-78) and in our discussion of the facts *supra* at Section II(B), which are replete with uncontested facts regarding Gilead’s wide spectrum of prices charged to both domestic and international purchasers of its HCV drugs. To suggest that there is something neutral about its HCV drug prices, historical or prospective, is not just disingenuous—it is an outright misstatement. It is for this reason that Gilead’s reliance on *Williams v. State Div. of State Police*, No. 10-3478, 2012 U.S. Dist. LEXIS 72457 (D.N.J. May 24, 2012) is so troublesome. Aside from the fact that Williams arose under the Fair Housing Act (“FHA”)²¹ and was an unpublished, per curiam, opinion, the facts alleged in Williams are dramatically different from the facts in the instant case.

The *Williams* plaintiffs were residents and shareholders in a cooperative association, whose board proposed restructuring it into condominiums due to its financial difficulties. *Id.* at *2. In connection with that transaction, all of the existing residents/shareholders had the choice of either purchasing their unit and participating in the conversion, or receiving a cash payment in a sum equal to the (allegedly diminished) fair market value of their unit as a cooperative. *Id.* at *6. Even though all of the plaintiffs had signed an agreement indicating their intention to participate in the conversion plan (and one of them cast a vote supporting it), they filed a lawsuit after they

²¹ While courts have sometimes found the case law interpreting the FHA to be useful in interpreting the Rehabilitation Act, the Supreme Court has cautioned that “too facile an assimilation of [§ 504] law into [the Fair Housing Act] must be resisted.” *Elliott v. Athens*, 960 F.2d 975, 981 (11th Cir. 1992) (quoting *Alexander v. Choate*, 469 U.S. 287, 290 n.7 (1985)).

were later unable to obtain financing sufficient to allow them to purchase their units and participate in the plan. *Williams*, 1996 U.S. App. LEXIS 31004, at *6. The plaintiffs attempted to show that the plan had a disparate impact on protected groups by citing *ex post* data and statistics which showed that “blacks and disabled persons suffered disproportionately...” *Id.* at *10. In affirming the district court’s dismissal of the plaintiffs’ FHA claim on a motion for summary judgment, the Fourth Circuit held “that when the alleged injury to a claimant is solely the product of a facially neutral price (e.g., a price that does not vary depending on one’s race, handicap, or other status protected by the Fair Housing Act), no claim based on disparate impact can be brought under the Fair Housing Act.” *Id.* at *12.

In *Williams* the unit prices were uniform and transparent, in sharp contrast to the patently wide-ranging Hepatitis C drug prices charged by Gilead, both domestically and abroad, that are opaque, inscrutable and, in no manner, “neutral.” Moreover, the Fourth Circuit’s account of what it viewed as a non-actionable “facially neutral price” – which it described as a price that “does not vary” depending on one’s disability – illustrates why it is inapposite here. As Plaintiffs have alleged (and Gilead’s brief has now confirmed), it is *only* persons with a disability (HCV) who would ever purchase Sovaldi or Harvoni. So, unlike the *Williams* plaintiffs who had to rely on statistical evidence to show that this transaction plan adversely affected a larger number of people in protected groups than in non-protected groups, under the circumstances of this case *all* of the affected HCV patients are members of a protected group. In contrast to the high prices in *Williams* that were offered to everyone, the excessive prices offered by Gilead for its HCV drugs are only to those who, by definition, have a disability. As such, *Williams* does not allow Gilead to price discriminate among persons suffering from the same Hepatitis C disability. Such conduct violates Section 504 of the Rehabilitation Act. In addition, *Williams* does not address the

“exclus[ion] of participation” and the “deni[al] [of] benefits” language of the ACA. *See* 42 U.S.C. § 18116(a), *cf.*, *Rumble, supra*.

ii. Gilead’s policy arguments regarding price discrimination are unpersuasive.

Gilead’s real objective in its “neutral” price section is to admonish the Court to not become involved in “sweeping judicial price regulation.” Def. Mem. at 8. Further, they assert in a vapid discourse on economics that “[a]ny price will exclude those who lack the means or willingness to pay” and that “[t]aken to its logical conclusion, the claim that it is discriminatory to set prices that are inaccessible to some is a mandate that a product be available at or below cost to all.” Is Gilead serious making these arguments in a case where the cost of producing a pill is \$1.00 and it is being sold by Gilead for \$1,000?²² Are there no limits to Gilead’s corporate avarice?

Contrary to Gilead’s suggestion, the ACA, Rehabilitation Act and Civil Rights Act do not contain a special exception for situations where the alleged discrimination involves the price of a product or service. *See East, supra*. Gilead does not respond to the obvious question of what is the Court to do if there is a well-pled claim that Gilead’s pricing policies and practices have discriminated against a protected class of HCV victims. Is there no remedy for such violations? Is the Court somewhere precluded from fashioning an appropriate remedy because the vehicle for discrimination is price? The response to these questions must be a resounding “No.”

Gilead warns against this Court attempting to determine a “fair price” for its HCV drugs, asserting that would be tantamount to the Court acting as a “rate-setting regulatory agency.” Def. Mem. at 10 (quoting *Pacific Bell Telephone Co. v. Linkline Communications, Inc.*, 555 U.S. 438,

²² *See* n.2, *supra* (Compendium, Article 3).

452 (2009)).²³ Gilead misses the objectives of this litigation. Plaintiffs do not seek to have this Court set prices for Gilead's drugs. Gilead has already set its prices in different geographic locations, with various purchasers and utilizing a host of vehicles. Its sharply discounted prices in Egypt (\$900) and numerous other countries are presumably economically sustainable as are presumably its recently negotiated, but undisclosed, discounted prices to a group of domestic PBMs.²⁴ Plaintiffs will present that and related pricing data to the Court through expert testimony in order to establish non-discriminatory prices for the Class. This would be consistent with numerous cases that have measured damages by reference to what the "fair price" would have been absent the alleged wrongful conduct. *See, e.g., In re Polyester Staple Antitrust Litig.*, No. 03-1516, 2004 U.S. Dist. LEXIS 32281, at *12 (W.D.N.C. Feb. 5, 2004) ("...antitrust damages in price-fixing cases are typically measured by 'the difference between the price paid and the market or fair price... under natural conditions' in the absence of a conspiracy.") (quoting *Chattanooga Foundry & Pipe Works v. City of Atlanta*, 203 U.S. 390 (1906)); *Computer Assocs. Int'l v. American Fundware*, 831 F. Supp. 1516, 1526-1527 (D. Colo. 1993) (proper measure of damages in misappropriation of trade secrets cases involves determining "what the parties would

²³ The dicta from *Linkline* on which Gilead relies is inapposite. The Supreme Court there was grappling with the highly-complicated question of whether a "price-squeeze" by a vertically integrated firm (*i.e.*, one that both sells to competitors at the wholesale level and competes with them at the retail level) could give rise to a Sherman Act claim by a competitor. 555 U.S. at 442. In concluding that in most instances it could not, Chief Justice John Roberts described the difficulties that would arise if such a claim were viable: "recognizing price-squeeze claims would require courts simultaneously to police both the wholesale and retail prices to ensure that rival firms are not being squeezed. And courts would be aiming at a moving target, since it is the interaction between these two prices that may result in a squeeze." *Id.* at 453. The Court further added – in the passage relied upon by Gilead – that the complex price-squeeze analysis would likely require a court to determine if a defendant left "its rivals a 'fair' or 'adequate' margin between the wholesale price and the retail price." *Id.* at 454. In sharp contrast, the question here of whether the prices Gilead charges for Harvoni and Sovaldi are "fair" is a much more straightforward inquiry.

²⁴ As noted above, it has been reported that Gilead can produce Sovaldi for as little as \$1 per pill. *See supra* n.2.

have agreed to as a fair price for licensing the defendant to put the trade secret to the use the defendant intended at the time the misappropriation took place.”) (quoting *University Computing Co. v. Lykes-Youngstown Corp.*, 504 F.2d 518, 530 (5th Cir. 1974)); *Mid-Michigan Computer Sys. v. Marc Glassman, Inc.*, 416 F.3d 505, 510-511 (6th Cir. 2005). See also, *Vermont Microsys., Inc., v. Autodesk, Inc.*, 88 F.3d 142, 151 (2d Cir. 1996) (“A reasonable royalty award attempts to measure a hypothetically agreed value of what the defendant wrongfully obtained from the plaintiff...the court calculates what the parties would have agreed to as a fair licensing price at the time that the misappropriation occurred.”).

Gilead is entitled to earn a reasonable profit. Under the unique and remarkable circumstances here, its reasonable profit will be calculated by reference to its actual historical pricing decisions.

2. Violation of the ACA Based on the Civil Rights Act.

As noted above, Gilead does not address Plaintiffs’ contention that its discriminatory conduct also had a disparate impact on minorities, in violation of Title VI of the Civil Rights Act of 1964. See FAC ¶ 133. The Civil Rights Act was enacted to eliminate financial participation of the federal government in illegal discrimination. See *NAACP v. Wilmington Medical Center, Inc.*, 453 F. Supp. 330, 347 (D. Del. 1978) (citing 110 Cong. Rec. 7062 (1964) (remarks of Senator Pastore)). Title VI mandates that “No person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.” 42 U.S.C. § 2000d. In order to establish a prima facie case under Title VI, Plaintiffs must show that they: (1) were members of a protected class, (2) were qualified for the educational benefit or program at issue, (3) and that they suffered an adverse action, (4) which occurred under

circumstances giving rise to an inference of discrimination. *Blunt v. Lower Merion Sch. Dist.*, 767 F.3d 247, 314 (3d Cir. 2014). As discussed below, Gilead's conduct has violated this statute.

a. Gilead's Pricing Practices Harmed Members of One or More Protected Classes.

There is no dispute that African Americans – a group adversely affected by Gilead's pricing practices – are a protected class covered by the Civil Rights Act. *See e.g., Wheeler v. Commonwealth Dep't of Labor & Indus.*, No. 10-2022, 2012 U.S. Dist. LEXIS 43481, at *12 (E.D. Pa. Mar. 29, 2012) ("Wheeler, an African-American, is a member of a protected class."); *Williams v. State Div. of State Police*, No. 10-3478, 2012 U.S. Dist. LEXIS 72457, at *24 (D.N.J. May 24, 2012) ("Here, Mr. Williams is clearly a member of a protected class as an African American."). Members of the Class were prescribed both Sovaldi and Harvoni, but were ultimately unable to receive the drugs due to cost. FAC ¶¶ 21, 22, 65, 77, 78, 133.

b. Gilead's Conduct Constitutes Intentional Discrimination

In order to state a claim under Title VI based on a facially neutral policy that has a disparate impact on a protected class, a plaintiff must "plead facts that would support an inference of discrimination" and must "allege that he was treated differently from similarly situated [persons] who are not members of a protected class." *See Daniel v. Office of the President of the United States*, No. 14-1330, 2014 U.S. Dist. LEXIS 123276, at *13 (E.D. Pa. Sept. 3, 2014) (citations omitted). To establish a violation of Title VI of the Civil Rights Act of 1964, 42 U.S.C. § 2000d, a private plaintiff is also required to prove intentional discrimination. *See Alexander v. Sandoval*, 532 U.S. 275, 280 (2001). Plaintiffs bringing a Civil Rights Act claim may establish intentional discrimination with a showing of deliberate indifference. *See e.g., Griffin v. Berks County Hous. Auth.*, No. 10-cv-05740, 2014 U.S. Dist. LEXIS 168993, at *26 (E.D. Pa. Dec. 4, 2014); *see also Blunt v. Lower Merion Sch. Dist.*, 767 F.3d 247, 272-73 (3d Cir. 2014); *S.H. v.*

Lower Merion Sch. Dist., 729 F.3d 248, 264 n.24 (3d Cir. 2013). Plaintiffs have pleaded facts sufficient to establish Gilead’s deliberate indifference.

In order to demonstrate intentional discrimination based on deliberate indifference, plaintiffs are required to show that “the defendant had knowledge of the alleged misconduct [(that is, underlying racial discrimination or harassment)] and the power to correct it but nonetheless failed to do so.” *Griffin*, 2014 U.S. Dist. LEXIS 168993, at *26 (quotation marks omitted) (quoting *Blunt*, 767 F.3d at 273). Deliberate indifference does not require a showing of “personal ill will or animosity” but must be a “deliberate choice, rather than negligence or bureaucratic inaction.” *See S.H.*, 728 F.3d at 263 (citations omitted). Here, Plaintiffs have established that Gilead knew that Hepatitis C victims are disproportionately African Americans, knew of the impact its pricing practices had on racial minorities, that it made a deliberate choice to price Sovaldi and Harvoni in a manner that would negatively impact racial minorities’ access to those drugs, and that Gilead – as the sole patent holder of Sovaldi and Harvoni – had the power to correct its misconduct, but failed to do so. *See, e.g.*, FAC ¶¶ 133, 137-139.

First, Gilead has knowledge that harm to a federally protected right is substantially likely. Section 2000d of the Civil Rights Act states that no person may be excluded from participation in, or denied the benefits of, or be subjected to discrimination under any program receiving federal financial assistance on the grounds of race, color, or national origin. As discussed in the FAC, it is a well-known fact that HCV occurrence is disproportionately high among African Americans. The Centers for Disease Control and Prevention has stated that African Americans have “substantially higher rate of chronic Hepatitis C infection than Caucasians and other ethnic groups.”²⁵ Although only comprising 13% of the U.S. population, nearly 22% of those diagnosed

²⁵ See <http://www.cdc.gov/hepatitis/Populations/AAC-HepC.htm> (last visited Feb. 24, 2015).

with HCV – plus the scores of individuals who have not yet been diagnosed – are African American.²⁶ Moreover, HCV prevalence is substantially higher in prison inmates than the general United States population; one in three inmates are infected with HCV and African Americans make up approximately 44.3% of the prison population in the United States.²⁷ Not only is HCV prevalence substantially higher among African Americans, but chronic liver disease, which is often HCV related, is a leading cause of death among African Americans aged 45 to 64.²⁸ Any counterargument that such statistical information is irrelevant or only relevant to a disparate impact claim is unavailing, as evidence of disparate impact may serve as an “important starting point” for determining the existence of intentional discrimination.²⁹ *See Blunt v. Lower Merion Sch. Dist.*, 826 F. Supp. 2d 749, 759 (E.D. Pa. 2011) (citing *Gen. Bldg. Contractors Assoc. v. Pennsylvania*, 458 U.S. 375, 397 (1982)).

Second, Gilead not only has the power to correct access to its drugs, but it purports to have the *sole power* to do so. Gilead is the only owner of the patents for the active ingredients of Sovaldi and Harvoni. Indeed, the primary argument advanced by Gilead to dismiss this case is that it has the ability to charge whatever price it wants. As such, Gilead’s conduct easily meets the second requirement of the deliberate indifference test.

²⁶ *See*

http://www.nmanet.org/index.php?option=com_content&view=article&id=291&Itemid=420 (last visited Feb. 24, 2015).

²⁷ *See* (<http://www.cdc.gov/hepatitis/HCV/PDFs/HepCIncarcerationFactSheet-BW.pdf>) (last visited Feb. 24, 2015); <http://onlinelibrary.wiley.com/doi/10.1002/hep.22509/pdf>) (last visited Feb. 24, 2015).

²⁸ *See*

http://www.nmanet.org/index.php?option=com_content&view=article&id=291&Itemid=420 (last visited Feb. 24, 2015).

²⁹ Gilead relies on *Blunt v. Lower Merion Sch. Dist.*, 826 F. Supp. 2d at 759-60 for the proposition that statistical evidence alone is not enough to create a *prima facie* case under Title VI. That decision, however, was rendered on a motion for summary judgment with the full benefit of discovery and, as such, is inapposite.

Whether viewed through the lens of the Rehabilitation Act or Civil Rights Act, the result is the same: Gilead has unlawfully discriminated against members of a protected class, and through its pricing policies has denied members of a protected class from participating in and/or receiving the benefits of a program or activity receiving federal financial assistance – all in violation of the ACA. This claim, accordingly, should not be dismissed.

B. Plaintiffs State Viable Claims Under State Law.

Gilead next argues that all of Plaintiffs' state law claims are “preempted by federal patent law,” and none is viable on the merits. As discussed below, these arguments are unpersuasive.

1. Gilead’s Purported Patent Protection Does Not Allow it to Charge Exorbitant Prices

The Supreme Court of the United States has ““made clear that the patent laws provide a limited right to exclude others from making, using, or selling a claimed invention for a limited period of time, [and] afford no affirmative right to make, use, and sell a patented invention.””

TransCore, LP v. Elec. Transaction Consultants Corp., 563 F.3d 1271, 1275 (Fed. Cir. 2009) (quoting *Leatherman Tool Group Inc. v. Cooper Indus., Inc.*, 131 F.3d 1011, 1015 (Fed. Cir. 1997)). This is consistent with the statutory framework for patents, which provides that a patent only provides a “right to exclude others from making, using, offering for sale, or selling the invention throughout the United States..., and, if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States, or importing into the United States, products made by that process, referring to the specification for the particulars thereof.” 35 U.S.C. § 154(a)(1). Similarly, the infringement enforcement section states that “whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.” 35 U.S.C. § 271(a). Statutory damages for

infringement are to be in an amount “adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court.” 35 U.S.C. § 284. Nowhere do the patent laws contain a mechanism authorizing a patent holder to charge whatever price it wants, however exorbitant it may be. Instead, the “limited” rights associated with patent ownership clearly only extend to the ability to exclude infringers from the market.

There is jurisprudence recognizing this distinction between a patent holder’s right to exclude infringers and efforts to price gouge. One such case – *Biotechnology Indus. Org. v. District of Columbia* – is described by Gilead in its brief as having “particular significance here.” *See* Def. Mem. at 12. In that case, the Federal Circuit addressed a pre-enforcement challenge to proposed legislation by the District of Columbia City Council that prohibited any patented prescription drug from being sold in Washington, D.C. at an “excessive price.”³⁰ 496 F.3d 1362, 1365 (Fed. Cir. 2007). The law was challenged by a pharmaceutical trade association on the basis that it was preempted by the federal patent laws. *Id.* In the initial panel decision, the court noted that “[t]here is no express provision in the patent statute that prohibits states from regulating the price of patented goods; indeed, “the federal patent laws do not create any affirmative right to make, use, or sell anything.”” *Id.* at 1372 (quoting *Leatherman Tool Group, Inc. v. Cooper Indus., Inc.*, 131 F.3d 1011, 1015 (Fed. Cir. 1997)). It also noted that the “patent laws are not intended merely to shift wealth from the public to inventors.” *Id.* at 1373.

³⁰ The statute was premised on a legislative finding that the ““excessive prices of prescription drugs in the District of Columbia is [sic] threatening the health and welfare of the residents of the District...”” *Biotechnology Indus. Org.*, 496 F.3d at 1365 (quoting D.C. CODE § 28-4551). It provided that a *prima facie* case of excessive pricing “shall be established where the wholesale price of a patented prescription drug in the District is over 30% higher than the comparable price in any high income country in which the product is protected by patents or other exclusive marketing rights.” *Id.* (quoting D.C. CODE § 28-4554(a)).

Nevertheless, the panel concluded that the proposed D.C. law was inconsistent with the overall objective of the patent laws to provide an incentive for innovation, and held that it was preempted.³¹ *Id.* at 1372-73.

The District of Columbia then sought rehearing *en banc* of the panel's decision, which was denied in a separate opinion. *Biotechnology Indus. Org. v. District of Columbia*, 505 F.3d 1343 (Fed. Cir. 2007). Significantly, Judge Timothy B. Dyk wrote a dissenting opinion which explained that the panel's opinion went too far in that it "suggests that even legitimate price regulation is invalid." *Id.* at 1348. Judge Dyk then went on to criticize the majority's conclusion that the proposed legislation would create a conflict with "a supposed policy of the patent law to allow patent holders to reap maximum profits during the term of the limited monopoly on use of the invention." *Id.* at 1350. As he explained, this is incorrect:

[T]he panel errs in suggesting that the purpose of the patent statutes is to allow a patentee to reap maximum profits during the exclusivity period because "the only limitation on the size of the carrot [the patentee's profit during the exclusivity period] should be the dictates of the marketplace." **A patent grant is designed not to allow the patent holder to exploit the grant for the maximum profit that the market will bear, but merely to confer a right of exclusivity.** The panel's assertion to the contrary is inconsistent with longstanding Supreme Court precedent.

Id. at 1350-51 (emphasis supplied). As such, in Judge Dyk's view, a state law prohibiting price discrimination of patented products does "not in any way interfere with any patent holder's right to exclusivity" in that it "does not authorize any other person to make, use, or sell any patented

³¹ The analysis underlying the majority's conclusion in *Biotechnology Indus.* is distinguishable because the invalidity of the D.C. statute was attributable to its "poor drafting." *Biotechnology Indus. Org. v. District of Columbia*, 505 F.3d 1343, 1348 (Fed. Cir. 2007) (Dyk, J., dissenting). But even if this analysis could be read to apply to Plaintiffs' state law claims, it would have no bearing on Plaintiffs' federal claim brought pursuant to the ACA. See *Biotechnology Indus. Org.*, 496 F.3d at 1371 ("...as between District statutes and superior enactments by Congress, the general principles of preemption from Supremacy Clause law apply.").

products.” *Id.* at 1351.³²

So too here, Plaintiffs are not contesting Gilead’s right – to the extent it holds valid patents – to “exclude” anyone from “making, using, [or] offering for sale” an infringing product. 35 U.S.C. § 154(a)(1). To the contrary, Plaintiffs are simply contending that Gilead cannot exploit its patent rights by charging exorbitant prices. This is not a concept that is limited to a dissenting opinion in the Federal Circuit; it has been recognized by the Supreme Court in decisions dating back over 160 years ago. *See Leatherman Tool Group v. Cooper Indus.*, 131 F.3d 1011, 1015 (Fed. Cir. 1997) (“As the Supreme Court has stated, ‘the franchise which the patent grants, consists altogether in the right to exclude everyone from making, using, or vending the thing patented, without the permission of the patentee. This is all that he obtains by the patent.’”) (quoting *Bloomer v. McQuewan*, 55 U.S. 539, 548, 14 L. Ed. 532 (1852)).

Gilead’s attempt to use the patent laws to justify the exorbitant prices it charges for Sovaldi and Harvoni is also directly at odds with cases that have held that a patent holder is not immune from other laws, such as the Sherman Act.³³ *See Eastman Kodak Co. v. Image Tech. Servs.*, 504 U.S. 451, 479 n.29 (1992) (“The Court has held many times that power gained through some natural and legal advantage such as a patent, copyright, or business acumen can give rise to liability if ‘a seller exploits his dominant position in one market to expand his empire into the next.’”) (quoting *Times-Picayune Publishing Co. v. United States*, 345 U.S. 594, 611

³² For this reason, the line of cases cited at page 13 of Gilead’s brief dealing with conflict preemption are inapplicable under the circumstances of this case.

³³ Relatedly, Gilead acknowledges several times in its brief that Plaintiffs’ FAC no longer asserts a claim under the Sherman Act. *See, e.g.*, Def. Mem. at 1, 14. For this reason, its heavy reliance on the passage in *Trinko* which recognized that the antitrust laws cannot be used to challenge the ability of a monopolist to charge whatever price it wants (absent anticompetitive conduct) is unavailing. *See Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004). Justice Scalia’s opinion in that case does not say that charging excessive prices cannot be challenged if it violates another statute or law.

(1953)); *Image Tech. Servs. v. Eastman Kodak Co.*, 125 F.3d 1195, 1215 (9th Cir. 1997) (“neither patent nor copyright holders are immune from antitrust liability...”). Indeed, the Supreme Court recently set forth the circumstances under which an ostensibly valid patent holder could be subject to antitrust liability for entering into a reverse payment arrangement with a claimed infringer. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2230 (2013). If Gilead’s view of the law was correct, any state law that prohibits price gouging would be ineffectual whenever it involved a product that happens to be subject to patent protection.³⁴ As explained above, the limited rights of exclusion afforded under the patent laws do not translate into blanket immunity for Gilead to engage in selective price gouging, particularly under the extraordinary circumstances presented here.

While Plaintiffs no longer assert a Sherman Act claim, Gilead cites *Schor v. Abbott Laboratories*, for the proposition that “[t]he price of [a patented drug] cannot violate the Sherman Act: a patent holder is entitled to charge whatever the traffic will bear.” *See* Def. Mem. at 14 (quoting *Schor*, 457 F.3d 608, 610 (7th Cir. 2006)). Aside from addressing a claim not at issue in this case, the Seventh Circuit’s dicta about patent rights does not support Gilead’s position that Plaintiffs’ state law claims are preempted here. That case involved HIV drugs that acted as protease inhibitors which hampered the virus’ ability to copy itself into additional cells. *Id.* at 609. Abbott had patents on two such drugs: (1) Norvir, which can be administered as a stand-alone drug but may also have serious adverse side effects, and (2) Kaletra, which is a combination drug that includes both Norvir plus a protease inhibitor called lopinavir. *See id.* The plaintiffs alleged that Abbott engaged in a scheme to monopolize the entire market for protease inhibitors by charging an unduly high price for Norvir alone and an unduly low price for Kaletra

³⁴ See, e.g., 73 Pa. C.S. § 232.1, *et seq.*, which bans businesses from charging excessive prices during a declared state of emergency.

(*i.e.*, Kaletra sells for less than a cocktail that could be made by combining Norvir with a protease inhibitor from another supplier). *Id.* The district court held (and the Seventh Circuit affirmed) that these allegations of “monopoly leveraging” did not violate the Sherman Act because the plaintiff did not allege additional anticompetitive conduct. *Id.*

There are significant factual and legal differences between this case and *Schor*. Absent in *Schor* is the egregious nature of the price gouging at issue here. The annual cost of Norvir to a U.S. consumer is approximately \$7,811, a fraction of the price of either Harvoni or Sovaldi.³⁵ There are also no allegations of a “monopoly leveraging” scheme in this case, whereby some combination of the drug is available at an “unduly low” price (as Kaletra was in *Schor*). Similarly, since it pre-dated the 2010 enactment of the Affordable Care Act, the *Schor* court had no occasion to address the anti-discrimination claims at issue here. *Schor* does not support dismissal of Plaintiffs’ state law claims. In sum, Gilead cannot rely on its “limited” rights as a patent holder to immunize its conduct here.

2. Gilead Has Engaged in Unfair and Unlawful Conduct Under the California Unfair Competition Law.

The FAC asserts two counts for violations of the California Unfair Competition Law, CAL. BUS. & PROF. CODE § 17200, *et seq.* (the “UCL”). The first claim (Count IV) is premised on Gilead’s “unlawful” conduct. *See* FAC ¶¶ 147-154. Gilead concedes that this claim can be premised upon the violation of another law. *See* Def. Mem. at 14. *See also, Rose v. Bank of America, N.A.*, 57 Cal. 4th 390, 396 (Cal. 2013) (“By proscribing ‘any unlawful’ business practice, [Business and Professions Code] ‘section 17200 ‘borrows’ violations of other laws and treats them as unlawful practices’ that the [UCL] makes independently actionable.”) (citations omitted), *cert. denied, Bank of Am., N.A. v. Rose*, 134 S. Ct. 2870 (2014). Gilead’s sole basis for

³⁵ <http://keionline.org/node/1536> (last visited Feb. 3, 2015).

dismissal of the “unlawful” portion of the UCL claim is that Plaintiffs are unable to state a predicate claim for violation of the ACA. *See id.* at 14-15. Because, as discussed above, Plaintiffs have done so, it follows that Gilead’s request to dismiss this claim for this reason should be rejected.

Plaintiffs’ second UCL claim (Count V) is based upon the “unfair” business acts and practices of Gilead. FAC ¶¶ 155-161. Gilead’s argument is premised on Plaintiffs’ failure to “tether” Gilead’s unfair conduct to an underlying violation of law as well as the lack of precedent for using the UCL as a rate-regulation statute. Def. Mem. at 15. Gilead’s argument fails for three reasons: Plaintiffs have established Gilead’s conduct violates the ACA; tethering unfair conduct to an underlying statutory violation is not the only avenue to maintaining a claim under the UCL; and Plaintiffs also seek injunctive relief in the form of pricing transparency, undercutting the suggestion that Plaintiffs are seeking to use the UCL as a rate-regulation statute.

First, Plaintiffs have established that Gilead’s conduct violates the ACA. *See* Section IV(A), *supra*. As Gilead admits in its brief, tethering unfair conduct to an underlying statutory violation is sufficient to state a claim under the UCL. Def. Mem. at 16. Gilead’s violation of the ACA is sufficient to satisfy the UCL tethering test and thus Plaintiffs’ UCL claim survives on this basis alone. *See Scripps Clinic v. Superior Court*, 108 Cal. App. 4th 917, 939 (Cal. App. 4th Dist. 2003) (discussing tethering requirement).

Second, “[t]here is a split of authority on what constitutes an ‘unfair’ practice” under the UCL. *See Jolley v. Chase Home Finance, LLC*, 213 Cal. App. 4th 872, 907 (Cal. App. 1st Dist. 2013). Indeed, some cases hold that an unfair practice is “one that offends established public policy, that is immoral, unethical, oppressive, unscrupulous, or substantially injurious to consumers, or that has an impact on the victim that outweighs the defendant’s reasons,

justifications, and motives for the practice.” *Id.* (collecting cases); *see also Pastoria v. Nationwide Ins.*, 112 Cal. App. 4th 1490, 1498 (Cal. App. 2d Dist. 2003) (adopting unfairness test that weighed the competing interests of wrongdoer and the impact of the act or practice on the alleged victim). In *Pastoria*, the court noted that a full factual record was required before weighing competing interests to determine unfairness. *Id.* (“Defendants have not had an opportunity to state their reasons, justifications, or motives for selling the insurance without giving the plaintiffs notice of imminent changes before the plaintiffs purchased the insurance. At this point, we cannot say that the defendants’ motives, reasons, or justifications for failing to notify the plaintiffs outweigh the plaintiffs’ interest in being fully informed of the impending changes.”).

This case is not at a procedural stage where a full factual record has yet been developed as to the unfairness of Gilead’s conduct and the deleterious impact of that conduct on members of the Class. The Complaint allegations and the Factual Background, *supra* at Section III, contain immutable and uncontested facts that support, even at this early stage, the conclusion that Gilead has committed unfair practices within the meaning of the UCL. In particular, given the admittedly significant social policy issues implicated by Gilead’s conduct (*see, e.g.*, Section II(e), *supra*), it is more than ironic that Gilead again, as it unsuccessfully did with the SEC in response to the UAW Trust’s shareholder proposal, seeks to trivialize the import and repercussions of its extortionist pricing conduct by citing to UCL precedent involving relatively ordinary facts.

An example is Gilead’s reliance on *Boris v. Wal-Mart Stores, Inc.*, 35 F. Supp. 3d 1163 (C.D. Cal 2014) misplaced. *See* Def. Mem. at 17. That case involved a two medications – one labeled “Equate Migraine” and the other “Extra Strength Headache Relief” (“ES”) – both of which contained the exact same active ingredients, but were sold at different price points. 35 F.

Supp. 3d at 1166. According to the court, “the gravamen of Plaintiffs' case is that by charging more for [“Equate Migraine”] and using the color red on its packaging, Wal-Mart deceived Plaintiffs into believing Equate Migraine was more effective than the lower-priced, green-packaged [ES] when, in fact, both medications contain the same active ingredients in the same doses...” *Id.* at 1168. The plaintiffs alleged that this was “unfair” and they were injured because “no reasonable consumer would pay more than \$9 for Equate Migraine when he could pay less than \$3 for [ES] unless he or she believed Equate Migraine was more effective than [ES]” *Id.* In pertinent part, the court dismissed the plaintiffs’ “unfairness” claim under the UCL because they did “not point[] to any specific constitutional, statutory, or regulatory provision that embodies a policy that Equate Migraine's price and red packaging violate.” *Id.* at 1171.

Boris is readily distinguishable if for no other reason than the pedestrian facts underlying the case. The *Boris* court recognized, “unfairness cases predicated on public policy...require[s] that the public policy which is a predicate to the action must be 'tethered' to specific constitutional, statutory or regulatory provisions.” *Boris*, 35 F. Supp. 3d at 1171 (quoting *Durell v. Sharp Healthcare*, 183 Cal. App. 4th 1350 (2010)). The plaintiffs in *Boris* were unable to make this showing. Plaintiffs here can “tether” their UCL unfairness claim to significant public policy issues implicated by Gilead’s misconduct as well as the viability of the alleged statutory ACA violations. Thus, the *Boris* court’s concerns with addressing nonjusticiable “political questions” are not present because Congress has already done so in enacting the ACA. *Id.* at 1171-72. There are also obvious factual differences between this case and *Boris*: Plaintiffs’ claims here do not involve “a consumer’s assumptions about [the efficacy of] a product,” *id.* at 1166, or a challenge as to the differential in the price points at which a merchant sells two similar but differently-named products, *id.* at 1172, n.3, and, of course, they do not involve the sale of an over-the-

counter drug to treat headaches.

The UCL ultimately requires the Court to “weigh the utility of the defendant’s conduct against the gravity of the harm to the alleged victim.” *State Farm Fire & Casualty Co. v. Superior Court*, 45 Cal. App. 4th 1093, 1104 (Cal. App. 2d Dist. 1996). Here, Plaintiffs have alleged that Gilead’s pricing practices are discriminatory, have the potential to bankrupt segments of the U.S. health care industry (FAC ¶ 129), and are ultimately depriving millions of Americans from lifesaving access to Sovaldi and Harvoni (FAC ¶ 16). Plaintiffs further allege that Gilead has engaged in this conduct for the sole reason of increasing profits inflating its bottom line. FAC ¶ 59. Such a reason does not justify Gilead’s harm to Plaintiffs and the Class here and is unfair conduct under the UCL.

Third, Plaintiffs also seek injunctive relief that requires Gilead to provide transparency regarding its pricing of Sovaldi and Harvoni. FAC, Prayer for Relief ¶ (e). The text of the UCL expressly grants courts the power to enjoin a business from engaging in unfair competition. CAL BUS. & PROF. § 17203. California courts have interpreted this provision as “broad power to . . . enjoin on-going wrongful business conduct in whatever context such activity might occur.” *Nelson v. Pearson Ford Co.*, 186 Cal. App. 4th 983, 1015 (Cal. App. 4th Dist. 2010) (citation omitted). In order to obtain such relief, plaintiffs are required to show “that the wrongful conduct alleged in the complaint is ongoing or likely to recur.” *Id.* at 1015-16. Plaintiffs have alleged that if Gilead’s conduct is left unchecked, it has the potential to bankrupt segments of the U.S. health care system (FAC ¶ 129) and that it will prevent many of the *several million* Americans living with hepatitis C from obtaining access to Gilead’s drugs (FAC ¶ 16). Plaintiffs’ proposed relief – transparency regarding the pricing of Sovaldi and Harvoni – is also not the type of relief that would require “a trial court to assume the functions of an administrative

agency, or to interfere with the functions of an administrative agency.” *Blue Cross of California, Inc. v. Superior Court*, 180 Cal. App. 4th 1237, 1258 (Cal. App. 2d Dist. 2009).

Plaintiffs are also not requesting that the court “determin[e] complex economic policy.” *Id.* Plaintiffs are simply seeking the disclosure of facts that are already within Gilead’s control. Gilead also contends that SEPTA does not have standing to pursue its UCL claim, arguing that SEPTA obtained the benefit of its bargain and thus has no standing to pursue a claim pursuant to the UCL. Def. Mem. at 18-19. It is well-settled that Plaintiffs need only demonstrate “some form of economic injury” to have standing under the UCL. *Kwikset Corp. v. Superior Court*, 51 Cal. 4th 310, 323 (Cal. 2011). Economic injury is satisfied when a party “has alleged or proven a personal, individualized loss of money or property in any nontrivial amount.” *Id.* at 325. Here, SEPTA has alleged it has overpaid for Gilead’s HCV drugs that were priced in violation of state and federal law.³⁶ FAC ¶¶ 16, 20, 59.

In *Clayworth v. Pfizer, Inc.*, pharmacies were found to have UCL standing by paying excessive prices. 49 Cal. 4th 758, 788 (Cal. 2010). The court observed that drug manufacturers rely on pharmacies to distribute their drugs such that the pharmacies had “indirect business dealings with Manufacturers.” *Id.* at 788. The pharmacies alleged they lost money by paying overcharges due to defendant’s unfair competition (there, the defendant’s price-fixing conspiracy). *Id.* In challenging the pharmacies’ standing, the defendant argued that the pharmacies suffered no compensable loss “because they were able to mitigate fully any injury by passing on the overcharges.” *Id.* at 789. The court rejected this, stating it “conflate[d] the issue

³⁶ In fact, it was just reported in the *Philadelphia Inquirer* today that SEPTA increased its annual prescription drug budget by 12% to address rising prescription drug costs, in part due to the pricing of Gilead’s Hep C drugs. See http://www.philly.com/philly/business/20150320_Labor_health-care_costs_boost_SEPTA_budget.html (last visited Mar. 20, 2015).

of standing with the issue of the remedies to which a party may be entitled. That a party may ultimately be unable to prove a right to damages (or, here, restitution) does not demonstrate that it lacks standing to argue for its entitlement to them.” *Id.* Here, there can be no rational assertion that SEPTA mitigated its loss. SEPTA’s health plan is self-funded and it is that plan that overpaid for Gilead’s drugs due to Gilead’s unfair pricing practices. FAC ¶¶ 16, 20, 59. Thus, SEPTA has standing to pursue its UCL claim.

3. The FAC Pleads a Viable Claim for Unjust Enrichment.

Gilead states it is unsure which state law applies to Plaintiffs’ unjust enrichment claims. Def. Mem. at 19. For purposes of their claims for unjust enrichment, Plaintiffs’ claims also arise under California law. To the extent the court finds that California law does not apply to all members of the class, then Plaintiffs’ unjust enrichment claims arise under the laws of their home states: Pennsylvania for Plaintiffs Jane Doe and SEPTA, and Arizona for Plaintiff John Doe.³⁷ Unjust enrichment is appropriate to remedy unfair pricing practices where a defendant unfairly manipulates the market to achieve larger profits than it otherwise would have. *See Siegel v. Shell Oil Co.*, 480 F. Supp. 2d 1034, 1044 (N.D. Ill. 2007) (finding “facts consistent with [those] allegations could establish that Defendants unjustly enriched themselves.”).

Gilead argues that there is no independent cause of action in California for unjust enrichment. Def. Mem. at 19. Gilead, however, misstates the current state of the law. In California, courts are split as to whether unjust enrichment can be an independent claim. *See Baggett v. Hewlett-Packard Co.*, 582 F. Supp. 2d 1261, 1270 (C.D. Cal. 2007) (citation omitted). Indeed, in *Ghirardo v. Antonioli*, the Supreme Court of California held plaintiffs may state a claim for unjust enrichment. 14 Cal. 4th 39, 50 (1996); *see also In re TFT-LCD (Flat Panel*

Antitrust Litig., No. 10-5625, 2011 U.S. Dist. LEXIS 105151, at *21 (N.D. Cal. Sept. 15, 2011) (permitting unjust enrichment claims because plaintiffs also invoked another valid theory of recovery and noting that courts have generally allowed claims for unjust enrichment to proceed). As such, Plaintiffs need to establish: (1) that Gilead received a benefit; and (2) that Gilead unjustly retained the benefit at the expense of another. *Baggett*, 582 F. Supp. 2d at 1270. Plaintiffs Jane Doe and SEPTA have alleged that Plaintiffs enriched Gilead (FAC ¶¶ 125-126); Gilead appreciated such benefits through the exorbitant profits it generated and retained from Plaintiffs and the Class (FAC ¶ 126); and that Gilead’s pricing was done in bad faith and solely to inflate its own bottom line, making it unjust for Gilead to retain the absurd profit margin from its sales of Sovaldi and Harvoni (FAC ¶¶ 127-128).

Alternatively, under Pennsylvania law, both Jane Doe and SEPTA have plead sufficient facts to support a claim for unjust enrichment. “[U]nder Pennsylvania law, to state a claim for unjust enrichment, the plaintiff must allege ‘benefits conferred on one party by another, appreciation of such benefits by the recipient, and acceptance and retention of these benefits under such circumstances that it would be inequitable [or unjust] for the recipient to retain the benefits without payment of value.’” *Premier Payments Online, Inc. v. Payment Sys. Worldwide*, 848 F. Supp. 2d 513, 527 (E.D. Pa. 2012). Plaintiffs Jane Doe and SEPTA have alleged that Plaintiffs enriched Gilead (FAC ¶¶ 125-126); Gilead appreciated such benefits through the exorbitant profits it generated and retained from Plaintiffs and the Class (FAC ¶ 126); and that Gilead’s pricing was done in bad faith and solely to inflate its own bottom line, making it unjust for Gilead to retain the absurd profit margin from its sales of Sovaldi and Harvoni (FAC ¶¶ 127-128).

Under Arizona law, John Doe has plead sufficient facts to support a claim for unjust

enrichment. “A claim of unjust enrichment under Arizona law has five elements: ‘(1) an enrichment, (2) an impoverishment, (3) a connection between the enrichment and impoverishment, (4) the absence of justification for the enrichment and impoverishment, and (5) the absence of a remedy provided by law.’” *R. Prasad Indus. v. Flat Irons Env'l. Solutions Corp.*, No. 12-8261, 2013 U.S. Dist. LEXIS 71074, at *35 (D. Ariz. May 20, 2013) (citation omitted). Here, Plaintiff John Doe has alleged that Gilead was enriched as a result of its conduct (FAC ¶ 125); John Doe has suffered damages and those damages related to Gilead’s pricing practices (FAC ¶¶ 126-127); and that Gilead has no justification for its own enrichment and the resulting harm to Plaintiff and the Class (FAC ¶¶ 127-128). Lastly, a determination of element (5) “is contingent upon the resolution on the merits of [plaintiffs’] alternate claims,” the determination of which is premature at the motion to dismiss stage because the Court cannot be sure if plaintiffs other claims will be successful. *R. Prasad Indus.*, 2013 U.S. Dist. LEXIS 71074 at *36; FAC ¶ 129 (“Plaintiffs do not have an adequate alternative remedy available at law.”)).

In sum, Plaintiffs have plead viable unjust enrichment claims under California, Pennsylvania and Arizona law.

4. Gilead has Violated the Duty of Good Faith and Fair Dealing.

Finally, Gilead seeks dismissal of Count III of the FAC, which is a claim for breach of the duty of good faith and fair dealing. This claim is comprised of two basic, black letter law concepts. The first is the principle that all contracts contain a duty of the good faith and fair dealing.³⁸ See Def. Mem. at 20-21. As relevant here, Plaintiffs allege that this duty is implied in

³⁸ As with Plaintiffs’ claim for unjust enrichment, this claim is governed by the laws of Plaintiffs’ home states (Pennsylvania and Arizona). Like California, both of these states impose the covenant of good faith and fair dealing into all contracts. See *Myservice Force v. Am. Home Shield*, No. 10-6793, 2013 U.S. Dist. LEXIS 7027, at *41 (E.D. Pa. Jan. 17, 2013) (collecting cases); *Chocolates By Bernard, LLC v. Chocolaterie Bernard Callebaut Ltd.*, No. 2:10-cv-01298

contracts between Gilead and the wholesalers to whom it directly sells Harvoni and Sovaldi.³⁹

See FAC ¶¶ 141-142. The second component is that Plaintiffs and similarly situated HCV patients and purchasers were intended third party beneficiaries of these contracts, which Gilead is alleged to have breached by virtue of the exorbitant prices it charged. Once again, Gilead does not dispute the basic legal concept that third parties can pursue a breach of contract claim where they are intended third party beneficiaries of the contract.⁴⁰

Gilead argues instead that its “literal compliance” with its obligations under its contracts with wholesalers – presumably in the form of supplying the drugs for which it extracted excessive prices – is fatal to Plaintiffs’ breach of the duty of good faith and fair dealing claim. *See* Def. Mem. at 20. This overly simplistic view of the covenant of good faith and fair dealing is unfounded. In this regard, the district court’s opinion rejecting a substantially similar argument in the *In re Checking Account Overdraft Litig.* MDL is instructive. 694 F. Supp. 2d 1302, 1315 (S.D. Fla. 2010). The banks there sought dismissal of consumers’ claims for breach of the duty of good faith and fair dealing (which was based on the bank’s unilateral re-posting of their debit card transactions in non-chronological order to maximize overdraft revenue to the banks) on the grounds that this conduct was permitted by the literal language of the party’s account agreements. As the court explained:

Plaintiffs counter, and the Court agrees, that they do [not] seek to vary the language of the

JWS, 2013 U.S. Dist. LEXIS 96949 (D. Ariz. July 11, 2013) (“The covenant of good faith and fair dealing is generally implied in all contracts in Arizona.”). Gilead appears to agree with this concept. *See* Def. Mem. at 20-21 (citing California law).

³⁹ Plaintiff SEPTA’s purchases of Sovaldi and Harvoni were through a prescription benefit manager, and were not made directly from Gilead. *See* FAC ¶ 51.

⁴⁰ *See Martinez v. Cenlar FSB*, No. 13-00589-TUC-CKJ, 2014 U.S. Dist. LEXIS 122633, at *16-17 (D. Ariz. Sept. 3, 2014) (“As an intended third-party beneficiary of the Agreement, Plaintiff may be permitted to rely on the Agreement to pursue a claim for a breach of the covenant of good faith and fair dealing based in contract.”); *Elchik v. Akustica, Inc.*, No. 12-578, 2013 U.S. Dist. LEXIS 53376, *18 (W.D. Pa. Mar. 6, 2013).

contract, but rather to have the express contractual terms carried out in good faith. Plaintiffs do not ask the Court to tell the banks how to order transactions, but simply that the ordering must be carried out as contemplated by the covenant of good faith and fair dealing. There are a number of cases supporting the proposition that when one party is given discretion to act under a contract, said discretion must be exercised in good faith. .. Therefore, the Court will not dismiss the breach of contract claim on this basis.

Id. at 1315 (citations omitted). This reasoning from *In re Checking Account Overdraft Litig.* has since been adopted by another district court within this circuit. *See Hughes v. TD Bank, N.A.*, 856 F. Supp. 2d 673, 681-682 (D.N.J. 2012) (“Here, Plaintiffs do not want to vary express terms of the contract, but want TD Bank to exercise its contractual discretion reasonably. Plaintiffs allege that Defendant had the discretion to both reorder debit transactions and deny transactions that would overdraft the account. Defendant allegedly exercised its discretion solely to maximize fees, even when Plaintiffs were led to believe they had a positive account balance. Moreover, the overdraft fees were disproportionately larger than the size of the overdraft. These allegations violate Plaintiffs' reasonable expectations under the contract and plausibly state a claim. Accordingly, the Motion will be denied with respect to the breach of the implied covenant of good faith and fair dealing.”).

Here, just as in *In re Checking Account Overdraft Litig.* and *Hughes*, Plaintiffs are not seeking to alter any of the language in the contracts between Gilead and its distributors. Rather, they are seeking to have Gilead carry out the terms of these contracts reasonably and in good faith. Because Gilead claims to have the sole discretion to set whatever price it wants for Sovaldi and Harvoni – *see, e.g.*, Def. Mem. at 1, 13-16 – the covenant of good faith and fair dealing requires that it exercise this discretion in good faith. Plaintiffs have alleged that it has not done so, and Gilead does not persuasively argue otherwise.⁴¹

⁴¹ Nor has Gilead contested the notion that Plaintiffs have standing to enforce this duty even though they are third party beneficiaries of the contract, as opposed to being in direct privity.

With respect to Plaintiffs' assertion that they are intended third party beneficiaries of these contracts, Gilead contends that the FAC lacks "supporting allegations," does not offer any "factual allegations," and does "not name the parties to these contracts, identify the contracts' terms, [or] explain precisely how Gilead supposedly breached a duty of good faith in connection with the contracts..." *See* Def. Mem. at 20-21. Notably, even though Gilead itself is in a far better position to obtain any such proof than Plaintiffs, it does not put forth any "factual allegations" to support these positions. Regardless, the FAC alleges sufficient facts to support the reasonable inference that Plaintiffs and putative class members are intended third party beneficiaries of these contracts. At the pleading stage, this claim requires no more. *See Shumate, infra.* At most, Gilead has created genuine issues of material fact which, of course, should not be resolved in connection with its motion to dismiss. *See Shumate v. Twin Tier Hospitality, LLC*, 655 F. Supp. 2d 521, 536 (M.D. Pa. 2009) ("An examination of Pennsylvania contract law reveals that plaintiffs' amended complaint alleges facts sufficient to support the reasonable inference that Natasha and Naera Shumate were third-party beneficiaries of the proposed contract. However, given defendants' contention that Davis sought to rent a room solely for himself, a genuine issue of material fact remains regarding whether Natasha and Naera were *intended* third-party beneficiaries and therefore had sufficient rights under the contract to sustain a Section 1981 claim. Natasha and Naera Shumate have plead facts sufficient to survive a motion to dismiss per FED. R. CIV. P. 12(b)(6) and because a genuine issue of material fact remains regarding their status as intended third party beneficiaries, summary judgment in favor of defendants will be denied.") (emphasis added). Gilead's motion to dismiss this claim should,

Indeed, courts have recognized that "[i]ntended contract beneficiaries may 'possess the rights of parties to the contract'. ... Those rights may include the benefits of the implied covenant of good faith and fair dealing in a proper case." *Spinks v. Equity Residential Briarwood Apartments*, 171 Cal. App. 4th 1004, 1034 (Cal. App. 6th Dist. 2009) (internal citations omitted).

accordingly, be denied here too.

CONCLUSION

For the foregoing reasons, Gilead's motion to dismiss should be denied.

Dated: March 20, 2015

Respectfully submitted,

By: /s/ Nicholas E. Chimicles
Nicholas E. Chimicles
Benjamin F. Johns
Joseph B. Kenney
CHIMICLES & TIKELLIS LLP
One Haverford Centre
361 West Lancaster Avenue
Haverford, PA 19041
Telephone: (610) 642-8500
Facsimile: (610) 649-3633
Nick@chimicles.com
BFJ@chimicles.com
JBK@chimicles.com

Attorneys for Plaintiffs and the Class

CERTIFICATE OF SERVICE

I, Joseph B. Kenney, hereby certify that I caused the foregoing **PLAINTIFFS'** **MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANT'S MOTION TO DISMISS THE FIRST AMENDED CLASS ACTION COMPLAINT** to be filed before noon on March 20, 2015 using the Court's CM/ECF System, thereby causing it to be served upon all counsel of record in this case.

/s/ Joseph B. Kenney
Joseph B. Kenney